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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,472	10/30/2001	Yung-Nien Chang	397272000800	9279

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/020,472	Applicant(s) CHANG ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *7* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed June 30, 2003 (Paper No. 10) in response to the Office Action of March 26, 2003 is acknowledged and has been entered. Claim 2 has been cancelled and claims 16-21 have been added. Claims 1, 3-21 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No 9 is attached to the instant Office Action.

Drawings

The Office acknowledges the receipt of the corrected drawings, which have been approved by the Draftsperson.

Claim Rejections - 35 USC § 102

The rejection of claims 1-6, 11-13, 15 under 35 U.S.C. 102(b) as being anticipated by Yu et al. (Journal of Virology 1996; IDS Paper No. 5) **is maintained** for reasons of record.

Applicant arguments have been fully considered but are not deemed persuasive. Applicants have amended claim 1; applicant arguments are that the amended claims (1) require that the first nucleic acid construct comprises the tetracycline-regulated promoter/operator and (2) the cited references do not utilize the tetracycline promoter/operator.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the first,

second and third nucleic acid construct are in sequential order) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's arguments are that the first, second and third nucleic acid constructs are in sequential order in a cascade. This may be what applicants intends, however, the claims are drawn to a packaging cell comprising a first, second and third nucleic acid sequence the limitation as the claims are written is that the first or second product only needs to "be capable of" regulating the expression of the next sequence, that does not mean the they must regulate the expression of the next product it just implies that they may have that effect. Additionally, applicant's arguments are that the reference does not utilize the tetracycline promoter/operator, however, the claim limitations are such that the promoter/operator only needs "to be regulated by tetracycline" and therefore it does not have to be the tetracycline promoter/operator.

To reiterate, Yu et al. disclose a HIV packaging cell line (expressing at least one viral gene product). The cell line is transfected with a fusion protein consisting of a tetracycline repressor (tTA) and the activation domain of the herpes simplex virus VP16 domain (see page 4532, see figure 2 and results column 2). The gene of interest is controlled from the inducible promoter which consists of minimal CMV promoter coupled top the tetracycline operator sequences (see page 4533 column 1) the construct (which is now termed the first nucleic acid) expresses the product Rev, the Rev product in turn activates the production of Env from the REV inducible prompter (2^{nd} nucleic acid construct). The Rev protein also regulates the expression of the late proteins from the viral sequences in the HXBΔP1Δenv (2^{nd} nucleic acid construct). Here

the removal of tetracycline would first induce the expression of Rev which in turn would induce Env, Gag, Pol, Vif and Tat expression. Tat then activates the expression the packaging constructs HVP or HSN which are the third construct comprising a viral gene product (see figure 2). Therefore the instant invention is anticipated by Yu et al.

Claims 1, 3-8 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kafari et al. (Journal of Virology, 1999) **is withdrawn**.

Claim Rejections - 35 USC § 103

Claims 1-6, 9, 11-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (Journal of Virology 1996; IDS Paper No. 5) in view of Gosh et al. (Journal of Molecular Biology 1993) **is maintained** for reason of record.

Applicant arguments have been fully considered but are not deemed persuasive. Applicants have amended claim 1; applicant arguments are that the amended claims (1) require that the first nucleic acid construct comprises the tetracycline-regulated promoter/operator and (2) the cited references do not utilize the tetracycline promoter/operator.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the first, second and third nucleic acid construct are in sequential order) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's arguments are that the first, second and third

nucleic acid constructs are in sequential order in a cascade. This may be what applicants intends, however, the claims are drawn to a packaging cell comprising a first, second and third nucleic acid sequence the limitation as the claims are written is that the first or second product only needs to "be capable of" regulating the expression of the next sequence, that does not mean the they must regulate the expression of the next product it just implies that they may have that effect. Additionally, applicant's arguments are that the reference does not utilize the tetracycline promoter/operator, however, the claim limitations are such that the promoter/operator only needs "to be regulated by tetracycline" and therefore it does not have to be the tetracycline promoter/operator.

To reiterate, Yu et al. disclose a HIV packaging cell line (expressing at least one viral gene product). The cell line is transfected with a fusion protein consisting of a tetracycline repressor (tTA) and the activation domain of the herpes simplex virus VP16 domain (see page 4532, see figure 2 and results column 2). The gene of interest is controlled from the inducible promoter which consists of minimal CMV promoter coupled top the tetracycline operator sequences (see page 4533 column 1) the construct (which is now termed the first nucleic acid) expresses the product Rev, the Rev product in turn activates the production of Env from the REV inducible prompter (2^{nd} nucleic acid construct). The Rev protein also regulates the expression of the late proteins from the viral sequences in the HXBΔP1Δenv (2^{nd} nucleic acid construct). Here the removal of tetracycline would first induce the expression of Rev which in turn would induce Env, Gag, Pol, Vif and Tat expression. Tat then activates the expression the packaging constructs HVP or HSN which are the third construct comprising a viral gene product (see figure 2).

Gosh et al. teach that Tat and VP16 are interchangeable in their ability to transactivate the HIV-1 LTR. The reference does not teach a packing cell line.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the VP16 fusion protein construct taught by Yu et al with the Tat transactivator taught by Gosh et al. The inventions as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the instant invention is obvious over Yu et al. in view of Gosh et al.

The rejection of claims 1, 3-15 under 35 U.S.C. 103(a) as being unpatentable over Kafari et al. (Journal of Virology, 1999; IDS Paper No. 5) in view of Gosh et al. (Journal of Molecular Biology 1993) **is withdrawn**.

New Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) The claims are rejected because they utilize the term "capable of" which render the claims indefinite, because it is not clear whether nucleic acid constructs which do not have this ability are contemplated as well.

(2) The claims are indefinite because the ordinary artisan would not know what the constructs are and what they look like. Applicants have described the product only by their function alone. Functionality alone does not provide the ordinary artisan with any indication of what the structure looks like. Defining a product merely by a functional attribute fails to describe the product. The best way to describe a product would be to describe the structure in addition to some functional attributes. For example claiming a product that it is made of a rubber like material which is squishy and bouncy does not provide the ordinary artisan with any knowledge regarding the structure and the ordinary artisan would not know that the claimed product is defining a rubber ball. Therefore, claiming a product by function alone fails to describe the structure of the product. Without knowledge regrading the structure of the product the ordinary artisan cannot envision what is contemplated by the hypothetical (rubber ball) claim. Claims drawn to a product, which is made of a rubber like material that is squishy and bouncy would not lead the ordinary artisan to envision a rubber ball, the ordinary artisan could envision an eraser (which is usually square), a balloon (which may round but is not necessarily round), a computer mouse pad (of indeterminate shape) in addition to envisioning a rubber ball. By adding a structural feature (spherical) to the claimed product would provides more information to envision a rubber ball or a balloon, narrowing the possibilities. The claims are not clear although they are drawn to nucleic acids (which have a structure), however, the nucleic acid sequences contemplated have not been defined by their structural attributes. Additionally, it is not clear if all nucleic acid constructs can be found on the same DNA or if the term nucleic acid construct indicates individual nucleic acid structures.

(3) The claims are indefinite because the claim construction does not make it clear that the first or second products are necessarily present in the cell, the only product that is required is the "at least one viral gene product".

Claim Rejections - 35 USC § 102

Claims 7, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (Journal of Virology 1996; IDS Paper No. 5).

The instant invention is drawn to a packaging cell line comprising three nucleic acid sequences in which each sequence has an effect on the next sequence, in a cascade like fashion.

Yu et al. discloses a HIV packaging cell line (expressing at least one viral gene product). The cell line is transfected with a fusion protein consisting of a tetracycline repressor (tTA) and the activation domain of the herpes simplex virus VP16 domain (see page 4532, see figure 2 and results column 2). The gene of interest is controlled from the inducible promoter which consists of minimal CMV promoter coupled top the tetracycline operator sequences (see page 4533 column 1) the construct (the second nucleic acid construct) expresses the product Rev, the Rev product in turn activates the production of Env (the third nucleic acid construct) from the REV inducible prompter. The Rev protein of the also regulated the expression of the late proteins from the viral sequences in the HXBΔP1Δenv. Here the removal of tetracycline would first induce the expression of Rev which in turn would induce Env, Gag, Pol, Vif and Tat expression. Therefore the instant invention is anticipated by Yu et al.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER

9/22/03